



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Handwritten signature/initials

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,708	10/21/2003	Zhiyuan Gong	GLOF:007USC1	2707

32425 7590 05/10/2007
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

SINGH, ANOOP KUMAR

ART UNIT	PAPER NUMBER
----------	--------------

1632

MAIL DATE	DELIVERY MODE
-----------	---------------

05/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/605,708	Applicant(s) GONG ET AL.	
	Examiner Anoop Singh	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 05 February 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

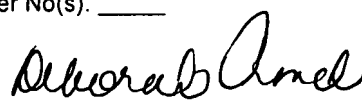
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____
 Claim(s) objected to: _____
 Claim(s) rejected: 1-16, 20, 21, 29-32 and 35-42.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.


 DEBORAH CROUCH
 PRIMARY EXAMINER
 GROUP 1800/630

Continuation of 5. Applicant's reply has overcome the following rejection(s): Claims 1-8, 16 and 36-42 rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS) and Bryan et al (US Patent no. 6436682 8/20/2002, filing date, 6/30/ 2000, effective filing date 3/ 27/ 1998) is withdrawn in view of cancellation of subject matter disclosed by cited references. Upon further consideration claims 1-16, 20-21, 29-32 and 35-42 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: The amendments to claims 1, 15, 36-36, 39 and arguments are not persuasive to overcome the rejections of claims 1-16, 20-21, 29-32 and 35-42, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of providing transgenic fish to the ornamental fish market comprising the step of (a) obtaining a transgenic zebrafish comprising a chimeric fluorescent gene operably linked to a muscle specific promoter selected from the list consisting of (i) zebrafish muscle creatine kinase gene promoter (SEQ ID NO: 8) such that said transgenic fish expresses fluorescent protein encoded by fluorescent gene in muscle, (ii) zebrafish fast skeletal myosin light chain 2 gene promoter (SEQ ID NO: 22) such that said transgenic fish expresses fluorescent protein encoded by fluorescent gene in skeletal muscle; at a level sufficient such that said transgenic fish fluoresces upon exposure to one or more light and (b) distributing said fish to the ornamental fish market, does not reasonably provide enablement for using any promoter or any other species of fish. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants do not provide arguments to address the issue of distributing transgenic fish comprising fluorescent gene under the control of any promoter. It was noted in previous office action dated 11/3/2006 that the breadth of claims 1 and 36 embrace distributing transgenic fish to ornamental fish market by obtaining transgenic fish comprising a fluorescent gene operably linked to any promoter, wherein said fish expresses fluorescent gene. As stated in previous office action, prior art teach numerous factors that potentially affect the transgenic frequency or expression levels in transgenic fish including (i) expression levels not strongly correlated to transgenic frequency; (ii) placement of construct (Higashijima et al (Dev Biol. 1997; 192(2): 289-99; art of record). The intent is not to say that transgenic fish or transgenic fish of other species cannot be made rather intent is to say that art of making transgenic ornamental fish for the distribution in ornamental fish market is unpredictable and dependent upon the expression level of fluorescent gene in different species. Furthermore, transgenics art generally recognizes that different promoter would have different expression levels that would be critical in determining whether a species of transgenic fish would fluoresces upon exposure to any light. Betancourt et al (Mol Mar Biol Biotechnol. 1993, 2(3): 181-8) states "elements from mammalian genes may not be properly recognized by the fish cellular machinery" and therefore they may work in unpredictable manner". It is noted that Betancourt et al suggest that vectors prepared to express foreign genes in transfected cultured fish cells and transgenic fish should preferably contain DNA sequences from fish genes or, alternatively, those sequences from mammalian genes that have been previously proved to be compatible with the fish cellular machinery (abstract). In the instant case, the specification teaches only two construct (2011 bp and 1338 bp) are capable of maintaining the high level of expression and highest expression was seen with only 2 -Kb promoter suggesting the importance of promoter region of 1338 bp to 2011 bp for conferring the highest promoter activity. In fact, applicants own specification describes that use of heterologous gene promoter from SV 40 and RSV and other promoters in studying zebrafish shows that expression pattern of a transgene in many case variable and unpredictable" (see page 6, 7 and 15 of the specification, paragraph 6 and also paragraph 28; emphasis added). The specification only provides guidance for using tissue specific promoters for obtaining expression of fluorescent fish at sufficient level. In absence of any specific guidance and given species-specific differences in the expression of various promoters as evidenced by Betancourt and instant specification, an artisan would have to perform undue experimentation and make new inventions in order to practice the method as claimed. In the instant case, the specific elements contemplated by the specification in the construction of vector for use in generating the transgenic ornamental fish were discovered by Applicant to overcome the art recognized unpredictability of using other promoters in achieving sustained expression of transgene in zebrafish. In fact, prior art and specification reports that not all promoters function well in fish. Absent of evidence to the contrary, it is not clear whether different promoters as embraced by instant claims would be functional in fish of different species in the same manner as they have been demonstrated in other organisms. It is emphasized that the breadth of instant claims are not directed to a method of making transgenic fish rather they are directed to a method for providing transgenic ornamental fish that fluoresces upon exposure to different light which requires expression of fluorescence gene at sufficient level. It is noted that the unpredictability of a particular art area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). It is also well established in case law that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 1013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). Thus, in view of prior art and teaching in the specification, it is apparent that choice of a promoter could greatly effect the level of expression in transgenic ornamental fish. Given such differences in the expression of a fluorescent gene as embraced by the claims, particularly when taken with the lack of guidance in the specification, it would require undue experimentation to establish the level of the fluorescent gene expression, the consequence of that expression and therefore its suitability for distribution in ornamental fish market.

Claims 1-16, 20-21, 29-32 and 35-41 remain provisionally rejected on the ground of non statutory double patenting over claims 7-20 of co pending Application No. 09/913, 898 (now US patent 7135613, dated 11/14/2006). It is noted that co pending application no 09/913,898 has been issued as US patent after mailing of final rejection. It is also noted that applicants have not responded to any of the previous double patenting rejection. In absence of any argument, nonstatutory double patenting rejection is maintained for the reasons of the record. This is a provisional double patenting rejection. The subject matter claimed in the instant application is fully disclosed in the referenced co pending application and would be covered by patent granted on that co pending application. It is noted that the referenced co pending application and the instant application are claiming common subject matter, because both sets of claims encompass transgenic ornamental fish that has utility in the ornamental fish market. Therefore, it would be obvious for an artisan to distribute the transgenic fish disclosed in the application no 09/913,898 (US 7135613) to ornamental fish market

Anoop Singh
AU 1632